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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,509	05/21/2002	Eric Paul Krenning	0702-020040	6829

7590 08/18/2004

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EXAMINER

HUI SAN MING R

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 08/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

514.

Office Action Summary

Application No.

10/031,509

Applicant(s)

KRENNING ET AL.

Examiner

San-ming Hui

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 53-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 53-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendments filed June 3, 2004 have been entered. The cancellation of claims 21-52 is acknowledged. The addition of claims 53-64 is acknowledged.

The outstanding rejections under 35 USC 112, first and second paragraph and 35 USC 102 are withdrawn in view of the amendments filed June 3, 2004.

Claim Rejections - 35 USC § 103

Claims 53-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takami et al.

Takami et al. teaches composition containing 4-6 g of lysine and 4-7g of arginine in 100ml of parenteral solution (See col. 6, Table 5, H-0 and H-5 solution).

Takami et al. does not expressly teach the method of preparing such composition. Takami et al. does not expressly teach the amount of lysine as 10-45 grams and that of arginine as 15-45 grams.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate lysine and arginine, in the amount herein claimed, into one composition.

One of ordinary skill in the art would have been motivated to incorporate all herein claimed ingredients, i.e., lysine and arginine, in the amount herein claimed, into one composition. Composition containing lysine and arginine is taught by Takami et al. Simply mixing and dissolving the ingredient of lysine and

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arginine with other ingredients of Takami to form a parenteral solution would have been consider obvious as being within the purview of the skilled artisan. Furthermore, the optimization of result effect parameters (dosage range, dosing regimens) is obvious as being within the skill of the artisan.

Claims 53-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zaloga et al. (US Patent 5,576,287).

Zaloga et al. teaches lysinie and arginine as useful in impairing the absorption of protein in kidney and treating renal failure (See col. 5, lines 9-10, also lines 35-52). Zaloga et al. also teaches the amount of the amino acids, such as lysine and arginine, as 5-15g/l (See col. 5, line 65).

Zaloga et al. does not expressly teach the method of preparing the lysine/arginine contaitning composition. Zaloga et al. does not expressly teach the amount of lysine and that of arginine as about 25 grams.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate lysine and arginine, in the amount herein claimed, into one composition and method of inhibiting renal absorption of proteins.

One of ordinary skill in the art would have been motivated to incorporate lysine and arginine, in the amount herein claimed, into one composition and method of inhibiting renal absorption of proteins. Composition containing lysine and arginine is taught by Zaloga et al. as useful in inhibiting renal absorption of

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proteins. Simply mixing and dissolving the ingredient of lysine and arginine with other ingredients of Zalog et al. to form a parenteral solution would have been consider obvious as being within the purview of the skilled artisan. Furthermore, the optimization of result effect parameters (dosage range, dosing regimens) is obvious as being within the skill of the artisan, absent evidence to the contrary.

Response to Arguments

Applicant's arguments filed June 3, 2004 averring the claims herein only employ lysine and arginine have been fully considered but they are not persuasive. The claims as recited the transitional phrase comprising, which is an open-ended expression that allows other ingredients to be employed also. Applicant's arguments, which are directed to unclaimed limitations (the employment of only lysine and arginine), are considered moot. Possessing the teachings of the cited prior arts, one of ordinary skill in the art would have been motivated to employ the lysine-arginine composition in a method to inhibit renal reuptake(i.e., absorption) of proteins.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is

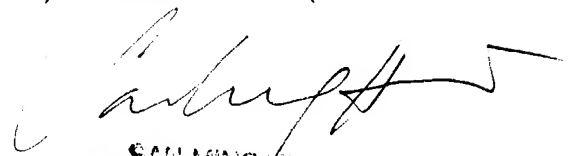
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filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SAN-MING HUI
PATENT EXAMINER

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San-ming Hui
Patent Examiner
Art Unit 1617